IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	David J. Yonce et al.	Examiner: Frances Oropeza
Serial No.:	10/723,254	Group Art Unit: 3766
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Customer No.: 45458		Confirmation No.: 6063
Title:	MORPHOLOGY-BASED DIAGNOSTIC MONITORING OF ELECTROGRAMS BY IMPLANTABLE CARDIAC DEVICE	

SUPPLEMENTAL REPLY BRIEF UNDER 37 C.F.R. § 41.41

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This Supplemental Reply Brief is filed in response to the Supplemental Examiner's Answer (hereinafter "Answer"), mailed on March 24, 2010, and supplements the Appeal Brief filed by the Appellant on January 21, 2009 and the Reply Brief filed on September 9, 2009. If necessary, please charge any additional fees or credit overpayments to Deposit Account No. 19-0743.

REMARKS

Appellant has reviewed the Supplemental Examiner's Answer, and believes the statements in the original Appeal Brief and Reply Brief remain accurate and compelling. In responding to the Supplemental Examiner's Answer, Appellant respectfully maintains that the Appeal Brief and Reply Brief, which is hereby incorporated by reference and reasserted in response, overcome the original grounds of rejections. Appellant offers the following comments regarding the assertions made in the Supplemental Examiner's Answer.

I.

In the Reply Brief, Appellant described independent claims 1 and 11 as reciting systems for computing and displaying electrograms of a patient in a manner that shows how the morphology of the electrograms changes over time or with respect to heart rate, respectively, referred to as representative electrograms, and asserted that the Levine reference does not disclose anything even remotely similar. In section 1, the Supplemental Examiner's Answer states:

> In response to the Appellant's argument that the references fail to show certain features of the Appellant's invention, it is noted that the features upon which applicant relies (i.e., showing how the morphology of the electrogram signal changes) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner notes the limitations in the claims of "generating representative electrograms" and "computing a representative electrogram" is not the same as "showing how the morphology of the electrogram signal changes" over time and with heart rate.

In section 4, the Supplemental Examiner's Answer states:

> On page 2 of the Reply Brief, the Appellant notes the discussion of the Q-T interval was not something specifically claimed, and was meant to give an example of a morphology change. The Examiner drew attention to the Q-T interval comment as the Appellant has emphasized morphology in the Appeal Brief and Reply Brief, when "morphology" is not a

> limitation found in the claims, and the Appellant has drawn on examples of morphology changes that are not even found in the specification apparently seeking to draw attention away from the claim language.

Appellant was certainly not seeking to draw attention away from the claim language. The purpose or utility of the systems recited by the pending claims is that such systems show how the morphology of electrograms changes over time or with respect to heart rate. Appellant regards as relevant to a section 103 rejection the fact that the Levine reference does not disclose anything that would accomplish a similar purpose. Also, a system that computes and displays representative electrograms as recited in the claims necessarily "shows how the morphology of electrograms changes over time or with respect to heart rate."

II.

Sections 5 through 8 of the Supplemental Examiner's Answer deal with Appellant's arguments that neither the Levine reference nor the incorporated Snell reference describes: 1) a system component configured to compute an average electrogram from a plurality of electrograms taken over some period of time, 2) a system component configured to compute a plurality of average electrograms for a plurality of discrete time intervals, referred to as representative electrograms, 3) a system component configured to aggregately display a plurality of electrograms, each of which having been recorded during different periods of time (i.e., the representative electrograms that represent the different discrete time intervals), or 4) a system component for computing a time average of electrograms recorded while the heart rate is within a particular range. Appellant's basic point is that neither Levine nor Snell describe time averaging electrograms for any purpose, much less the specific manners of performing the time averaging of electrograms in order to generate representative electrograms as recited in the claims.

The Examiner disagrees with Appellant's position with respect to this issue and asserts that the electrograms recorded at different locations during the same cardiac cycle as described in Levine (referred to in Levine as location-specific electrograms) are somehow actually

recorded at different times. In sections 5, 6, and 8 (and also section 9), the Supplemental Examiner's Answer states:

> Levine discloses a first sensing channel and three other sensing channels. The portion of the electrogram signal recorded through the different sensing channels are obtained from different locations in the heart and different waveforms occur at different times on each of the channels. For a heart beating 72 beats a minute, the cardiac cycle occurs over 0.834 seconds. Since the cardiac cycle includes excitation of the atria and ventricle in a stepwise pattern, and the excitation takes time to travel through the cardiac tissue, it is obvious the electrogram taken at the atrial location at a given time will be different from the electrogram taken at the ventricular location at the same time. It is the combination of the electrograms taken on four different channels over a span of, for example, the 0.834 seconds, the span read as comprising discrete intervals that become an average electrogram that is a time average.

In section 7, the Supplemental Examiner's Answer states:

> Levine discloses monitoring the cardiac cycle at three different locations (an atrial IEGM, a ventricular IEGM, and a surface ECG complex). These three signals are displayed as shown in figure 10 (column 16, line 35-37). The Examiner agrees the electrogram signal is a recording of the electrical potential generated by the heart over time as the heart polarizes and depolarizes during each heart cycle. The Examiner's point is that this polarization and depolarization occurs over time as the electrical stimulation wave travels across the heart, and the waveforms created at each of the different locations in the heart are different. When the ventricle, for example, begins to depolarize and the cells of the ventricle begin to contract, the atrial channel will not record this ventricular event, sometime called a far field event, until a later point in time when the electrical depolarization wave generated in the ventricle reaches the atria. Since the ventricular channel records the contraction originating in the ventricle at a first time and the atrial channel records the ventricular contraction as a far field wave at a second time, the electrograms related to the ventricular contraction are said to be recorded at different times, the difference in time being the time required for the

> electrical depolarization wave to travel from the ventricle to the atria. Since the cardiac cycle occurs over time and the cardiac cycle is measured at different locations providing different waveforms, the electrograms are read as being recorded over a plurality of discrete time intervals.

The above-quoted portions of the Supplemental Examiner's Answer make factually incorrect assertions and reflect a fundamental misunderstanding of the basic physics involved. Electrograms recorded by differently located electrodes during a single cardiac cycle reflect the same time course of cardiac depolarization and repolarization. For example, an atrial electrode detects atrial depolarization at the same time that a ventricular electrode does, but the resulting signal is smaller for the ventricular electrode than for the atrial electrode because the ventricular electrode is farther away from the atria. Such a smaller signal is sometimes called a far-field signal, as opposed to the near-field signal detected by an electrode in close proximity to the depolarizing or repolarizing tissue. When a wave of repolarization or depolarization travels through the heart, the electric potential in the extra-cellular fluid surrounding the heart changes over time, and this is what is reflected by an electrogram. When an electrogram is recorded by differently located electrodes during a single cardiac cycle, the morphology of the electrograms are different but reflect the same events at the same times. For example, when the atria depolarize during atrial contraction, the resulting potential change will be detected by an atrial electrode at the same time as by a ventricular electrode. (To be overly precise, the atrial and ventricular electrodes will detect the atrial depolarization after a time equal to the distance from the atria to each electrode divided by the speed of light.)

III.

Section 9 of the Supplemental Examiner's Answer deals with Appellant's arguments that neither the Levine reference nor the incorporated Snell reference describes: 1) a system component for computing a plurality of representative electrograms where each such representative electrogram is an average of electrograms recorded while the heart rate is within a different heart rate range, or 2) a system component configured to simultaneously display a plurality of electrograms, whether averaged or not, recorded while the heart rate is within

different heart rate ranges and to index the displayed electrograms by heart rate. The Supplemental Examiner's Answer states:

> Levine teaches electrograms can be grouped based on heart rate ranges enabling focus upon a single heart rate range, or different heart rate ranges (column 14, lines 31-34). Levine discloses displaying three different cardiac waveforms, an atrial IEGM, a ventricular IEGM, and a surface ECG complex, as shown in figure 10 (column 16, lines 35-37), hence cardiac data such as the display a plurality of electrograms recorded while the heart rate is within different heart rate ranges, indexed by heart rate is disclosed.

What Levine actually says at col. 14, lines 31-34 is: "The counters may have separate bins or registers for different heart rate ranges to permit location-specific histograms of intrinsic events to be recorded as a function of heart rate." The Levine reference makes a distinction between an "event" such as a paced or sensed event and an "IEGM" or intra-cardiac electrogram. Clearly, the counters described in the cited portion of Levine are for counting discrete events in order to construct histograms and not for recording electrograms. Also, Fig. 10 just shows an atrial electrogram, a ventricular electrogram, and a surface ECG recorded during the same cardiac cycle and in no way relates to the display of a plurality of electrograms recorded during different cardiac cycles and indexed by heart rate.

CONCLUSION

The pending claims subject to this appeal are believed patentable. Appellant respectfully submits that the claims are in condition for allowance and requests the Board issue an order to withdraw the rejections.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(847) 432-7302

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By / J. Kevin Parker /
J. Kevin Parker
Reg. No. 33,024

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Kate Gannon / Kate Gannon /

Name Signature